

REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of three of the period for response to the Office Action. Our deposit account order form in respect of the prescribed fee is enclosed.

The withdrawal of the finality of the prior rejection is acknowledged.

The Examiner noted applicants instructions to cancel claim 7 while also providing an amended claim 7. The Examiner is correct that applicants did not intend to cancel claim 7 but rather to provide it in the amended form. The Examiner further noted that applicants reference in the remarks to cancelling claim 3 but the amendment contained no such instruction. It is clear that the instruction to cancel claim 7 should have been to cancel claim 3. This Amendment contains a clear instruction to cancel claim 3.

The receipt of the Examiner initialed and signed IDS is acknowledged.

It is noted that the new Declaration submitted with our Amendment of January 3, 2001 is acceptable.

The Examiner rejected claims 3 and 6 to 15 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 has been deleted.

With respect to claim 6, it is submitted that it is clear in the context of this claim that the T-cell epitope is an integral part of the amino acid sequence. Claim 6 has been further amended to recite that the peptide contains the T-cell epitope.

Claim 7 currently is dependent on claim 5. It would appear that the claim should be dependent on claim 6, wherein there is adequate basis for the term "said peptide". Claim 7 now has been so amended.

With respect to the term "having an amino acid sequence which is that of a portion" utilized in claims 6 and 7, it is submitted that the terminology is clear in scope. These claims define the T-cell inducing HIV molecules. This is defined as a peptide which peptide has an amino acid sequence which is that of a portion of an HIV-1 antigen in the case of claim 6 or specifically Rev in the case of claim 7. These claims are simply defining the peptide.

The Examiner indicated that claim 12 is vague and indefinite with respect to the recitation "an amino acid corresponding to". The Examiner's suggestion for revision by way of deletion of this phrase has been adopted.

Having regard to the revisions made to the claims and the above submissions, it is submitted that claims 3 and 6 to 15, insofar as they remain in the application and in their amended form, can no longer be considered indefinite and hence the rejection thereof under 35 USC 112, second paragraph, should be withdrawn.

The Examiner maintained rejection of claims 1 and 3 to 15 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is more closely associated, to make and/or use the invention for the reasons of record in the prior Office Action.

It is not seen how any such rejection can be made with respect to the peptide claims 12 to 15. Claim 12 defines a peptide of defined amino acid sequence along with identification of specific sequences within the peptide which are T-cell epitopes, as demonstrated in the specification. Claims 13 and 14 define the peptide as a lipopeptide (claim 12) wherein the lipid is palmitoyl or cholesterol (claim 14). Claim 15 defines the lipopeptide as ones specifically described in the specification, namely CLP-175 or CLP-176. It is submitted that it is a sufficient written description and enablement of a peptide to provide its amino acid sequence, which is what applicants have provided. In addition, applicants have provided additional characterization of the peptide as containing three amino acid sequences which are T-cell epitopes. The determination of T-cell epitopes is readily achieved. The claims further define the peptide as a lipopeptide, the sequence for the specific CLP-175 and CLP-176 being given in Table 2. It is clear that claims 12 to 15 cannot be open to rejection under 35 USC 112, first paragraph.

With respect to claims 1 and 3 to 11, claim 3 has been deleted, so that the Examiner's discussion of this claim is moot.

The applicants invention as defined in claim 1 is the generation of an HIV-specific cytotoxic T-cell response in a host. It is acknowledged, as the Examiner states, that the entire "Background to the Invention" section of the specification

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refers to HIV vaccines and vaccinology. The applicants further acknowledge that the specification contains the statement:

"The present effort has turned to the design of HIV vaccines capable of eliciting cell-mediated immunity (CMI) and protocols for the use thereof."

However, these statements do not promise that the procedure of the invention is a vaccination procedure against HIV and neither does applicants data demonstrate the same. Applicants claim 1 specifically recites:

"A method of generating an HIV specific cytotoxic T-cell response in a host."

This is the scope of invention claimed. The applicants have demonstrated the generation of the HIV specific cytotoxic T-cell response specifically employing certain peptides and lipopeptides as claimed in the claims subsidiary to claim 1. The applicants do not promise and do not demonstrate that the HIV specific cytotoxic T-cell response leads to prevention of HIV infection. As earlier stated, the claims do not recite HIV infection therapy nor prevention of infection. It is not clear how the plain language of the claims cannot be considered persuasive.

The Examiner is correct that the cited prior art of Fahey et al, Fox and Haynes et al discuss the problems of providing protection HIV infection and that the ability to treat and/or prevent HIV infection is highly unpredictable and has met with very little success. But applicants claims are not cast that broadly. Applicants claims define the generation of a CTL response, which is demonstrated by applicants data. Applicants data is commensurate in scope with the language of the claims.

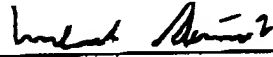
Having regard to the scope of the claims presented and the above discussion, it is submitted that claims 1 and 3 to 15, insofar as they remain in the application, and in their amended form, are fully enabled and hence the rejection thereof under 35 USC 112, first paragraph, should be withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

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It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 3 has been cancelled.

Claims 6, 7 and 12 have been amended as follows:

6. (Thrice Amended) The method of claim 1 wherein said T-cell inducing HIV molecule includes a peptide having an amino acid sequence which is that of a portion of an HIV-1 antigen, said peptide [and] containing at least one T-cell epitope.

7. (Thrice Amended) The method of claim 6 [5] wherein said peptide having an amino acid sequence which is that of a portion of the Rev protein of HIV-1.

12. (Thrice Amended) A peptide consisting of [an amino acid corresponding to] amino acids 52 to 116 (SEQ ID No:9) of the sequence of the Rev protein of HIV-1 LAI isolate and containing T-cell epitopes within amino acids 63 to 73 (SEQ ID NO:3), 74 to 83 (SEQ ID NO:5) and 102 to 110 (SEQ ID NO:8).